

4.2 – APPENDIX B: FEES RATES AND FEE PAYING SUBMISSION TRENDS

GDUFA Fee History

GDUFA directs FDA to collect revenue from four fee categories: ANDAs in the backlog as of October 1, 2012; DMFs; facilities, and applications (ANDA and PAS). This requires FDA to establish user fee rates by fee category, application type, location, and business operation as specified in the statute. FDA published the following fee rates based on statutory target revenues and estimates of fee-paying submissions.

TABLE 9: TRENDS IN APPLICATION, DMF, AND FACILITY FEES³

Fiscal Year	Backlog Fee	DMF Fee	Domestic FDF Facility Fee	Foreign FDF Facility Fee	Domestic API Facility Fee	Foreign API Facility Fee	ANDA Fee	PAS Fee
2013	\$17,434	\$21,340	\$175,389	\$190,389	\$26,458	\$41,458	\$51,520	\$25,760
2014	N/A	\$31,460	\$220,152	\$235,152	\$34,515	\$49,515	\$63,860	\$31,930
2015	N/A	\$26,720	\$247,717	\$262,717	\$41,926	\$56,926	\$58,730	\$29,370
2016	N/A	\$42,170	\$243,905	\$258,905	\$40,867	\$55,867	\$76,030	\$38,020

GDUFA Forecasted Versus Actual Fee-Paying Submissions

Table 10 depicts FDA's estimates of fee-paying units used in the *Federal Register* (FR) notices for setting GDUFA fees prospectively versus the actual number of fee-paying units received each year.

TABLE 10: TRENDS IN FORECASTED VS. ACTUAL FEE-PAYING APPLICATION, DMF, AND FACILITY FEES

Fiscal Year	Forecasted vs. Actual	Backlog Applications	DMFs	Domestic FDF Facilities	Foreign FDF Facilities	Domestic API Facilities	Foreign API Facilities	Applications
2013	FR	2,868	700	325	433	122	763	1,160
	Actual	2,851	1,808	283	324	124	901	1,143
2014	FR	N/A	583	315	433	128	775	1,149
	Actual	N/A	793	288	369	125	692	1,724
2015	FR	N/A	701	271	410	103	692	1,276
	Actual	N/A	740	299	399	126	715	655

³ FDA published FY 2016 human generic drug user fee rates on August 3, 2015, in the *Federal Register* <https://www.gpo.gov/fdsys/pkg/FR-2015-08-03/pdf/2015-18915.pdf>

Fiscal Year	Forecasted vs. Actual	Backlog Applications	DMFs	Domestic FDF Facilities	Foreign FDF Facilities	Domestic API Facilities	Foreign API Facilities	Applications
2016	FR	N/A	453	283	422	105	721	1,005
	Actual	N/A	529	298	396	114	709	976